

PATENT  
674538-2001

**REMARKS**

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The July 16, 2002 Office Action called for restriction from among the following:

- Group I: Claims 5, drawn to a method of regulating transcription comprising introducing into a plant cell an engineered zinc finger polypeptide fused to a transcriptional activator domain, classified in class 530, subclass 350;
- Group II: Claim 6, drawn to a method of regulating transcription comprising introducing into a plant cell an engineered zinc finger polypeptide fused to a transcriptional repressor domain, classified in class 530, subclass 350;
- Group III: Claims 15 and 22, drawn to a plant host cell and transgenic plant comprising a polynucleotide encoding an engineered zinc finger polypeptide fused to a transcriptional activator domain, classified in class 435, subclass 419; and,
- Group IV: Claims 16 and 23, drawn to a plant host cell and transgenic plant comprising a polynucleotide encoding an engineered zinc finger polypeptide fused to a transcriptional repressor domain, classified in class 800, subclass 298.

Additionally, the Office Action states that claims 1-4 and 9 link Groups I and II; and claims 7-8, 10-14 and 17-21 link Groups III-IV.

Group III is elected, with traverse. As it will herein be shown, the restriction requirement is improper.

The MPEP lists two criteria for a proper restriction requirement. First, the alleged inventions must be independent or distinct. MPEP § 803. Second, if search and examination of an entire application can be made without serious burden, the Examiner must examine [the entire application] on the merits. *Id.*

It is respectfully submitted that the restriction requirement does not meet either of these criteria.

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The Office Action states that the “inventions are distinct . . . because . . . [i]nventions I-IV are unrelated.” Groups I and II are stated to have different effects; while Groups I and II are segregated from groups III and IV on the basis of an allegedly different mode of operation.

35 U.S.C. § 121 states that, in order for restriction to be proper, two or more inventions must be independent and distinct (emphasis added). See also 37 C.F.R. §§ 1.141 (a) and 1.142 (a). The Restriction Requirement has made no showing that Groups I-IV are independent. For this reason alone, the Restriction requirement is improper and should be withdrawn.

Moreover, the Office’s assertions that the Groups are distinct (*i.e.*, unrelated) are also in error. The Office Action states that “inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation , different functions or different effects” (emphasis added). In the present case, the methods of Groups I and II can be used together. For example, to activate the expression of a first gene, while at the same time repressing the expression of a second gene, two engineered zinc finger polypeptides can be introduced into a plant cell: one comprising an activation domain and targeted to the first gene and the other comprising a repression domain and targeted to the second gene. The specification discloses both activating and repressing zinc finger polypeptides; and nowhere does the specification state that activation and repression are mutually exclusive possibilities. It is also evident, from the specification, that it is possible to obtain plant host cells and/or transgenic plants comprising multiple polynucleotides<sup>1</sup>, one or more of which encodes an activating zinc finger polypeptide and one or more of which encodes a repressing zinc finger polypeptide. Thus, the compositions of Groups III and IV are also capable of use together<sup>2</sup>. For the foregoing reasons, the restriction between Groups I and II is improper and should be withdrawn; moreover, any intended restriction between Group III and Group IV is also improper and should be withdrawn.

Furthermore, Groups I and II do not have different effects, as asserted in the Restriction Requirement; in both cases, transcription in a plant cell is regulated.

With respect to the division between Groups I and II on the one hand, and Groups III and IV on the other, the Office Action states:

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<sup>1</sup> See, for example, page 34, lines 18-19.

<sup>2</sup> Applicants note that no reason for the separation of Group III from Group IV was provided in the Office Action.

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Inventions III and IV have a different mode of operation from Inventions I and II. The methods of Inventions I and II comprise introducing an engineered zinc finger polypeptide directly into a plant cell, whereas the plant host cell and transgenic plant of Inventions III and IV comprise a polynucleotide encoding an engineered zinc finger polypeptide.

Office Action at 4.

Applicants respectfully disagree with this statement. The claims of Groups I-IV all have the same mode of operation: a zinc finger polypeptide binds to target DNA and regulates gene expression. This mode of operation is the same for Groups I-IV, regardless of whether the zinc finger polypeptide is introduced into the plant host cell or transgenic plant, or expressed from a polynucleotide introduced into the host cell or transgenic plant.. Furthermore, the mode of operation is also the same regardless of whether gene expression is activated or repressed; as in both cases the regulation occurs due to the binding of a zinc finger polypeptide to target DNA.

Consequently, the claims of Groups I and II, on the one hand, and Groups III and IV, on the other hand, do not have different modes of operation, as alleged in the Office Action. Again, for this reason alone, restriction is improper and should be withdrawn.

In summary, neither the first prong of the test for unrelatedness (incapable of use together) nor the second prong (different mode of operation, different function or different effect) has been satisfied by the Office. Accordingly, the Office has not met the first criterion for proper restriction (independent and distinct inventions). Therefore, the Requirement is improper and should be withdrawn.

With respect to the second criterion for restriction (undue burden on Examiner), the MPEP directs the Examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” MPEP §803.

Further still, the Examiner’s attention is respectfully drawn to MPEP §808.02 which states, “even with patentably distinct inventions, restriction is not (emphasis added) required unless one of the following reasons appears:

Separate classification;  
Separate status in the art; or  
Different field of search[.]”

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Indeed, Groups I and II are both classified in class 530, subclass 350. Furthermore, the claims of Groups I-IV all relate to engineered zinc finger polypeptides, such that any search and examination would be co-extensive, and would not place an undue burden on the Examiner.<sup>3</sup> Thus, neither of the criteria for proper restriction have been met.

Finally, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

### CONCLUSION

In view of the remarks presented herein, reconsideration and withdrawal of the restriction requirement are requested. Early and favorable consideration of the application on the merits, and allowance of the application are earnestly solicited.

Respectfully submitted,

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<sup>3</sup> Moreover, as stated hereinabove, the claims do not recite distinct and independent inventions.